



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,748	09/27/2005	Joel E White	700355-052696	9053
50828	7590	01/15/2008		
DAVID S. RESNICK 100 SUMMER STREET NIXON PEABODY LLP BOSTON, MA 02110-2131			EXAMINER SKOWRONEK, KARLHEINZ R	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 01/15/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,748	Applicant(s) WHITE ET AL.	
	Examiner Karlheinz R. Skowronek	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Status

Claims 19-29 are pending.

Claims 1-18 are cancelled.

Claims 19-29 are being examined.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 26 October 2007 was filed after the mailing date of the first action on the merits on 17 May 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

Response to Arguments

Applicant's arguments, see remarks p.9-10, filed 16 October 2007, with respect to the rejection of claims 26 and 27 as anticipated by Liebholz under 35 UCS 102 (e) have been fully considered and are persuasive. The rejection of claims 26 and 27 has been withdrawn based on amendments made to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is necessitated by amendment.

Claim 19, 20, 21, 24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebholz et al.(US Pat 7,029,852), in view of Melker et al.(US PG PUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100).

The claims are drawn to a sensing system comprising a nucleic acid base sensor array; an excitation light source; a detector; a sample chamber; a sampling means; a controller means; and an analyte detection means. In another embodiment, the identification algorithm includes pattern matching and report generation. In another embodiment, the system is remotely controlled. In an embodiment the fibrous substrate is silk.

Liebholz et al. shows a sensing system for the detection and identification of analytes in an air sample. The system of Liebholz et al. is composed of a nucleic acid

based sensor array formed through the use of multiple nucleic acid aptamers. The aptamers of Liebholz et al. are capable of detecting analytes. Liebholz et al. teach that upon binding of analyte the aptamers produce a detectable signal. The signal is detected by a detector array (col. 4, line 66-67). The sensor array is housed within a sampling chamber that is combined with a sampling means to bring air into contact with the sensor array (col. 5, line 38-48). In figure 8, Liebholz et al. shows a microcontroller/control means that is communication with the sampling means. The controller provides an analyte identification algorithm (col. 11, line 9-20). Liebholz et al. shows an embodiment in which the system is remotely controlled (figure 8). Liebholz et al. shows that a sampling algorithm is employed that opens or closes a trapdoor for a detector (col. 5 line 15-17). Liebholz et al. teach that the activation of the sensor array results a in a spatio-temporal response that is processed (col. 5, line 5-12). Liebholz et al. teach a processing system that produces a report.

Liebholz et al. do not teach a pattern matching that is a neural net or an nucleic acid array formed on a fibrous or particulate support.

Heynecker shows that nucleic acid microarrays can be formed on a number of different substrate. Heynecker shows that natural fibers such as silk are used a solid supports for microarray (col. 3, line 15-35).

Melker et al. teach the use of neural network for the generation of comparisons between the detected signal and a known pattern [0057].

It would have been obvious to modify the sensor apparatus of Liebholz et al. with the nucleic acid microarray substrates of Heynecker because all the claimed elements

were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective function; the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention. It would have been further obvious to modify the sensing system of Liebholz et al. with the neural network analysis of patterns of Melker et al. because Melker et al. shows neural networks have the advantage of enabling the device to understand the significance of sensor array output [0057]. Neural networks are used for self-learning of computational devices.

Response to Arguments

Applicant's arguments filed 16 October 2007 have been fully considered but they are not persuasive. Applicant argues that Liebholz et al. does not show a solid support that is fibrous or particulate. The argument is further supported by a declaration from the applicant stating in paragraph 12 of the declaration that the instantly claimed sensing system is designed to rely on analytes in the vapor which is distinguished over Liebholz. In paragraph 10 of the declaration filed 16 October 2007, applicant acknowledges that the aptamers of Liebholz detect harmful agents. Liebholz shows in the brief summary of the invention at col. 2, lines 23-30 that the aptamers are designed to detect and classify chemicals in fluids. As acknowledged by applicant at paragraph 9 of the declaration filed 16 October 2007, Liebholz et al. defines a fluid as being gaseous, vapor, or liquid at col. 2, line 60. However, based on the evidence provided in Liebholz, the aptamers of Liebholz are directed to bind gaseous and vaporous chemicals as well as other particles. Therefore, the statement by applicant at paragraph 12 of the declaration, that

the aptamers of the instant application are not intended to bind particles like the aptamers of Liebholz is not persuasive. "Affidavits or declarations are provided as evidence and must set forth facts, not merely conclusions. In re Pike and Morris, 84 USPQ 235 (CCPA 1949)." Heynecker shows that solid supports can be any substrate to which oligonucleotides, such as aptamers, can attached. Heynecker shows that in addition to glass, natural fibers like silk can be used as a solid support.

Applicant's arguments, see Remarks, filed 16 October 2007, with respect to the rejection of claims 19, 20, 21 and 24 as unpatentable over Liebholz et al. in view of Melker et al. under 35USC103(a) have been fully considered and are persuasive. The rejection of claims 19, 20, 21 and 24 has been withdrawn.

Applicant's arguments, see Remarks, filed 16 October 2007, with respect to the rejection of claims 20, 22, and 25 as unpatentable over Liebholz et al. in view of Melker et al. and in further view of Sunshine et al under 35USC103(a) have been fully considered and are persuasive. The rejection of claims 20, 22 and 25 has been withdrawn.

Applicant's arguments, see remarks, filed 16 October 2007, with respect to the rejection of claims 10 and 23 as unpatentable over Liebholz et al. in view of Melker et al. in further in view Vivekananda under 35USC103(a) have been fully considered and are persuasive. The rejection of claims 10 and 23 has been withdrawn.

The following rejection is necessitated by amendment.

Claims 20, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebholz et al. (US Pat 7,029,852), in view of Melker et al. (US PG PUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24, and 26- 28 above, and further in view of Sunshine et al. (US pat 6,234,006).

The claims are drawn to a sensing system comprising a nucleic acid base sensor array; an excitation light source; a detector; a sample chamber; a sampling means; a controller means; and an analyte detection means. In another embodiment, the identification algorithm includes pattern matching and report generation. In another embodiment, the system is remotely controlled.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 shows a sensing system for the detection and identification of analytes in an air sample. The system of Liebholz et al. is composed of a nucleic acid based sensor array formed through the use of multiple nucleic acid aptamers. The aptamers of Liebholz et al. are capable of detecting analytes. Liebholz et al. teach that upon binding of analyte the aptamers produce a detectable signal. The signal is detected by a detector array (col. 4, line 66-67). The sensor array is housed within a sampling chamber that is combined with a sampling means to bring air into contact with the sensor array (col. 5, line 38-48). In figure 8, Liebholz et al. shows a microcontroller/ control means that is communication with the sampling means. The controller provides an analyte identification algorithm (col. 11, line 9-20). Liebholz et al. shows an embodiment in which the system is remotely controlled (figure 8). Liebholz et al. shows that a sampling algorithm is employed that opens or closes a trapdoor for a

detector (col. 5 line 15-17). Liebholz et al. teach that the activation of the sensor array results a in a spatio-temporal response that is processed (col. 5, line 5-12). Liebholz et al. teach a processing system that produces a report.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 does not shows a sensing system that is specifically attached to a shipping container or that is hand held.

Sunshine et al. shows the application of a sensing system to a shipping container (col.24, line 51-52 and col. 25, line 27-28). Sunshine et al. shows a sensing system that is hand held (col. 2, line 60).

It would have been further obvious to modify the sensing system of Liebholz et al. in view of Melker et al. and in view of Heynecker with the portability of a handheld apparatus because Sunshine et al. shows that a handheld system provides the advantage of being small and light weight (abstract).

shows

The following rejection is necessitated by amendment.

Claims 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebholz et al.(US Pat 7,029,852), in view of Melker et al.(US PG PUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24 and 26-28 above, and further in view of Vivekananda (US PG PUB 2004/0023266).

The claims are drawn to a sensing system comprising a nucleic acid base sensor array; an excitation light source; a detector; a sample chamber; a sampling means; a

controller means; and an analyte detection means. In another embodiment, the identification algorithm includes pattern matching and report generation. In another embodiment, the system is remotely controlled.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 shows a sensing system for the detection and identification of analytes in an air sample. The system of Liebholz et al. is composed of a nucleic acid based sensor array formed through the use of multiple nucleic acid aptamers. The aptamers of Liebholz et al. are capable of detecting analytes. Liebholz et al. teach that upon binding of analyte the aptamers produce a detectable signal. The signal is detected by a detector array (col. 4, line 66-67). The sensor array is housed within a sampling chamber that is combined with a sampling means to bring air into contact with the sensor array (col. 5, line 38-48). In figure 8, Liebholz et al. shows a microcontroller/ control means that is communication with the sampling means. The controller provides an analyte identification algorithm (col. 11, line 9-20). Liebholz et al. shows an embodiment in which the system is remotely controlled (figure 8). Liebholz et al. shows that a sampling algorithm is employed that opens or closes a trapdoor for a detector (col. 5 line 15-17). Liebholz et al. teach that the activation of the sensor array results a in a spatio-temporal response that is processed (col. 5, line 5-12). Liebholz et al. teach a processing system that produces a report.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 does not shows a sensing system that is specifically attached to an X-ray screening machine.

Vivekananda et al. teach the system is applied to airport detection systems reading on X-ray screening machine [0029].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sensing system of Liebholz et al. in view of Melker et al. and in view of Heynecker with the application of the sensing system to a shipping container as in Vivekananda et al. because Vivekananda et al. teach the device fulfils the need for a rapid and sensitive method to detect and identify pathogenic spores of anthrax [0010-0011].

The following rejection is necessitated by amendment.

Claims 19, 20, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebholz et al.(US Pat 7,029,852), in view of Melker et al.(US PG PUB 2002/0177232) and in view of Heynecker (US PAT 6,057,100) as applied to claims 19, 20, 21, 24 and 26-28 above, and further in view of Klempner et al. (2002/0187464).

Claim 29 is directed to a substrate that is fiberglass.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 above shows a sensing system with a microarray formed on a fibrous or particulate substrate.

Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 above do not shows a substrate that is fiberglass.

Klempner et al. shows that microarray substrates can be formed from fiberglass [0049]. Klempner et al. shows that affinity ligand receptors can be oligonucleotides,

reading on aptamers [0014]. Klemptner et al. shows that the solid support can be particulate either beads, particles, or spheres.

It would have been obvious to one of ordinary skill in the art to modify the sensing apparatus of Liebholz et al. in view of Melker et al. and in view of Heynecker as applied to claims 19, 20, 21, 24 and 26-28 above with the fiberglass substrate of Klemptner et al. because the substitution of one type of solid support for another would have yielded predictable results.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Application/Control Number:
10/535,748
Art Unit: 1631

Page 12

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

14 January 2008
/KRS/
Karlheinz R. Skowronek
Assistant Examiner, Art Unit 1631

/John S. Brusca/
Primary Examiner
Art Unit 1631